Environmental Assessment of Hypobromous Acid (HOBr)

1. **Date** July 20, 2011

2. **Notifier** GE Betz dba. (GE Water & Process Technologies)

3. **Address** 4636 Somerton Road
Trevose, PA 19053

4. **Description of the proposed action:**

The action requested is the establishment of a clearance to permit the use of hypobromous acid as an antimicrobial additive in general process water for use on meat at ≤ 300 ppm Br_2 (182 ppm as HOBr) and poultry carcasses, parts, trim, organs and hides at ≤ 200 ppm Br_2 (121 ppm as HOBr). The product will be added to process spray water to reduce the numbers of and inhibit the growth of pathogens and other microorganisms for purposes of food safety.

HOBr is created in-situ at the customer location in a small batch reactor or automatically using chemical pumps into a water line using Spectrus OX1201 (40% Sodium Bromide, CAS Reg. No. 7647-15-6) and 12.5% sodium hypochlorite. Make up water may be ambient temperature or preheated up to 100 F. The bromide ion in the 40% sodium bromide precursor is inactive as Br^-. It must be oxidized to Br^+ in order to exert a toxicological effect on microorganisms. Conversion of Br^- to Br^+ will be achieved by feeding the 40% sodium bromide with 12.5% sodium hypochlorite (chlorine source). In water the oxidation of Br^- to Br^+ results in the formation of hypobromous acid (HOBr).

1) Spectrus OX1201 + Sodium Hypochlorite → Sodium Hypobromite + Sodium Chloride
NaBr + NaOCl → NaOBr + NaCl

2) In the presence of water NaOBr is reduced to hypobromous acid and sodium hydroxide:
NaOBr + H2O → HOBr + NaOH

To achieve 100% HOBr production, Spectrus OX1201 and 12.5% NaOCl need to be added at a mole ratio of 1:1 (Br:Cl) this correlates to 3.6 pounds of Spectrus OX1201 for every 1 gallon of 12.5% NaOCl. To ensure complete conversion into HOBr and thereby minimizing chlorine residual the dose will be recommended at 5 pounds Spectrus OX1201 for every gallon 12.5% NaOCl.

After undergoing chemical oxidation during use in the process water, the hypobromous acid converts to bromide ion (Br^-).

Customer location sites are located in urban industrial settings anywhere in the USA where animal slaughtering occurs. This substance would not require to be transported by truck or rail because it is created on-site at the customer's location. It is likely small food processors in a city locale will send their waste streams to municipal sewer systems. Large industrial food manufacturers likely have their own waste treatment systems, which include primary, secondary, and possibly even tertiary treatment.

The primary route of disposal for water that has been treated with hypobromous acid is through the processing plant wastewater treatment facility. A majority of beef and poultry processors treat their wastewater on site and ultimately discharge directly into receiving bodies of water or via land application. The plant processing water effluent empties into drains and may contain fat, blood, excrement and other organics and solids which may be fugitive from carcasses as they are washed, trimmed and further processed. The effluent stream is screened or filtered to remove gross solids and particulates prior to being sent to the Dissolved Air Floatation (DAF) systems. These combined systems are called the "pretreatment" system. This pretreated water is then sent to either a conventional aerobic wastewater treatment system or, in some cases, to anaerobic lagoon/digester system, both of which digest the balance of the soluble fats, proteins, and other organic constituents of the wastewater stream. Many if not most meat and poultry plants use the anaerobic digestion method of wastewater treatment (1). It should be noted that during several stages of wastewater pretreatment and subsequent digestion, the solids are removed from the wastewater by using several common techniques, but the great majority of the FCS would remain in the water phase due to the fact the FCS is hydrophilic as opposed to lipophilic in nature.

The Agency is aware of the substantial amount of scientific data available for the chemistry and environmental toxicology of sodium hypochlorite and hypochlorous acid, and the hypochlorites in general. The subject of this FCN is hypobromous acid, which also proportionally converts to hypobromite at pH values above 8. However, the chemistry and environmental toxicology of hypobromous acid is substantially similar or equivalent to hypochlorous acid, so the great majority of data for hypochlorous acid would be substantially identical to that of hypobromous acid (2).

5. Identification of the Chemical Substance

a. Identity of the Food Additive

(1)	Common Name	Hypobromous Acid (HOBr)
(2)	Chemical Name(s)	Bromanol, Hydroxidobromine
(3)	CAS No.	7681-52-9

b. Physical Properties

(1)	Color	Clear to pale to yellow
(2)	Clarity	Clear
(3)	Physical State	Liquid
(4)	pH neat	7.0 - 7.4
(5)	Specific Gravity @ 25 C	1.0

c. Establishment of Compositions

A characterization profile of HOBr using IR, UV, NMR etc. cannot be provided since 1) HOBr is generated in-situ in a reactor and 2) the instability of the compound makes it difficult to collect and analyze. Generation of HOBr using Spectrus OX1201 an aqueous 40% sodium bromide mixed with sodium hypochlorite is well documented and it is expected that mixing of these compounds per label or use instructions yields Hypobromous acid (HOBr, CAS Reg. No. 13517-11-8).

6. Introduction of Product Into the Environment:

Hypobromous acid is made *in situ* (on site) and therefore no substantive manufacturing data is available for this substance at or from remote locations. There are no extraordinary environmental circumstances pertaining to the production of hypobromous acid that warrant consideration. Given the locations of potential user's facilities, no effect on endangered species or rare floral or fauna is expected.

The use of the FCS, hypobromous acid, will not exceed 300 ppm as available bromine in the process water for meat processing. This equates to 133 ppm as available chlorine (Cl = 35.5 g/mole and Br = 79.9 g/mole). For poultry processing uses, the FCS will not exceed 200 ppm as total available bromine (or 90 ppm as total available chlorine). Hypobromous acid is a highly unstable and reactive compound and is not expected to survive the transition through meat and poultry processing due to the high organic demand which is inherent in these facilities (3, 4, 5). The half-life of hypobromous acid in low-demand tap water has been estimated by the EPA to be 125 hr~ (6). Hypobromous acid, being an unstable and reactive compound will decay to bromide ion (Br^-) very quickly in the presence of organic matter and ammonia, similarly to hypochlorous acid (2, 3, 4, 5). The maximum dose of this FCS in meat and poultry manufacturing is 300 ppm and 200 ppm respectively, as total available bromine (reported as HOBr). Hypobromous acid is 96.9 gms/mole (1+ 16 + 79.9). Bromide ion is 79.9 gms/mole; therefore, each ppm of HOBr will yield 0.82 ppm of bromide ion (79.9 / 96.9).

Referring to the equations in section 4 and based on the mole weights of each compound, the following amount of sodium chloride salt will be formed from sodium hypochlorite (NaOCl):

1. Every 1.0 lb. of 100% active NaOCl (bleach) fed yields 0.785 lbs. of salt (NaCl)

2. Adjusting for 12.5% active NaOCl = 0.098 lbs. of NaCl for every 1 lb. 12.5% NaOCl consumed.

Using the equations in Section 4, the above stoichiometric relationship between bleach and salt formation and the estimated water usage for each, poultry and meat processing, the quantity of HOBr and all breakdown by-products formed can be calculated as follows:

Poultry Processing:
Estimates for water usage in poultry processing and average number of birds processed per day were derived from (7) where an average of 26L/bird (6.87 gallons/bird) was reported by facilities.

For an average 200,000 bird/day processing plant the estimated water consumed = (200,000 birds/day) x (6.87 gallons/bird) = 1,374,000 gallons/day. The FCS is intended to be used at a maximum level of 121 ppm HOBr (200 ppm as total available bromine) for poultry. The FDA has examined dilution factors (DF) at poultry processing plants and found that 71 % of facilities had DF's > 100, and 96% had a DF of 20 or greater (8), (9). FDA has allowed a DF of 10 for use determining the EIC in previous EA submissions therefore the same DF of 10 will be used in this EA to determine EEC of the FCS in poultry processing (8), (9). The estimated discharges of the FCS and by-product salts are as follows:

- (1,374,000 gal process water/day) x (8.33 lbs/gal process water) = 11,445,420 lbs process water/day
- Assuming no degradation, concentration of HOBr in outfall =
  (121 ppm HOBr in treated process water)/10 (DF) = **12.1 ppm HoBr**
- 12.1 ppm HOBr x (0.82 Br-/HOBr)/10 (DF) = **9.9 ppm Br- ion**
- At 121 ppm HoBr: (0.40 NaBr)X x (96.9 g/mole HOBr/103 g/mole NaBr) = 121 ppm HOBr. Solving for X = 322 ppm 40% NaBr
- Using the feed ratio of bleach to 40% NaBr to get 100% HOBr stream the following is determined: 322 ppm 40% NaBr x (10.1 lbs 12.5% NaOCl) / (5.0 lbs 40% NaBr) = 650 ppm 12.5% NaOCl
- Concentration of NaCl discharged to outfall = (650 ppm NaOCl/day) x (0.125 active) x (0.785 ppm NaCl/100% active NaOCl) / 10 (DF) = **6.4 ppm NaCl**
- Concentration of NaOH discharged to outfall = 121 ppm HOBr x (40 g/mole NaOH/96.9 g/mole HOBr)/10 (DF) = **5.0 ppm NaOH**.

Meat Processing:
For a meat plant, 2000 head/day is a reasonably sized processing facility: An Agricultural Marketing Report, published in 2004, estimated that a small facility processed 20,000 head/year, a medium facility processed 480,000 head/year, and a large facility processed 1.5 million animals per year (10). This results in approximately 77 head/day in the small facility, 1,846 head/day at a medium facility, and 5,769 head/day at a large facility (based on normal hours @ 250 days). The FCS is intended to be used at a maximum level of 182 ppm HOBr (300 ppm as total available bromine) for meat processing.

According to (11) the amount of water consumed per unit of production was determined to be 1.62 to 9.0 m^3/t carcass. Using 1279 pounds as the average live weight killed/head of cattle (12) and knowing that 1 m^3 of water is equivalent to 264.17 gallons the amount of water consumed can be converted to gallons/head as follows:

Upper water use limit:
(9.0 m^3 water consumed/t carcass) x (1 t/2205 lbs) x (1279 lbs/head) = 5.22 m^3 water/head
(5.22 m^3 water/head) x (264.17 gallons/1m^3) = 1379 gal/head

Lower water use limit:
(1.62 m^3 water consumed/t carcass) x (1 t/2205 lbs) x (1279 lbs/head) = 0.94 m^3 water/head
(0.94 m^3 water/head) x (264.17 gallons/1m^3) = 248 gal/head

Of the total gallon per head water discharged, only a small portion of this is attributable from carcass process spray washing. Actual amount of water used to spray and cleanse the carcasses varies considerably on such factors as; overall cleanliness of the carcass, size and type of animal being slaughtered, manual vs. automated spray systems, spraying time, size of spray nozzle, and water pressure at the nozzle. These variables are evaluated by meat processing facilities when establishing Critical Control Points to fulfill their Hazard Analysis Critical Control Points Plan (HACCP). Conversation with Dr. Catherine N. Cutter (13) confirmed the variability in trying to estimate amount of water used to spray down a carcass. It was confirmed with Dr. Cutter that adult cattle carcasses would require the greatest amount of spray water thus represent the worst case scenario. For effective cleaning of carcass surfaces it is recommended that each side of beef be rinsed with warm water for 2 minutes. Smaller carcasses such as lamb, pork and/or veal should be washed for 1 minute (14). Assuming an average water flow rate of 10 GPM it can be calculated that for adult cattle 40 gallons of spray water are required to cleanse both sides while only 10 gallons are required to cleanse the smaller carcasses (14). Dr. Cutter did agree that a 2 minute spray wash would be a worst case scenario and stated that even for an adult cattle carcass a 15-45 second spray is more common. To ensure covering as best as possible all variables relating to gallons of FCS treated spray water used per head, it was decided to use the 40 gallon estimate as the total spray water treated with the FCS rather than a lower value based on a shorter spray time.
The estimated discharges of the FCS and by-product salts are as follows:

Upper water use limit:

- (1379 gal/head x 2000 head/day) x (8.33 lbs/gal process water) = 22,974,140 lbs process water/day (total)
- (40 gallons of FCS treated water/head) x (8.33 lbs/gal) x(2,000 head/day) = 666,400 pounds FCS treated water discharged/day
- 22,974,140 lbs process water / 666,400 pounds FCS treated water = 34:1 dilution factor (DF)
- Assuming no degradation, concentration of HOBr in outfall = (182 ppm HOBr)/34 (DF) = **5.4 ppm HOBr**
- Concentration of Br^- ion in outfall = 5.4 ppm HOBr x 0.82 Br-/HOBr = **4.4 ppm Br^- ion**
- At 182 ppm HOBr: (0.40 NaBr)X x (96.9 g/mole HOBr/103 g/mole NaBr) = 182 ppm HOBr. Solving for X = 484 ppm 40% NaBr

- Using the feed ratio of bleach to 40% NaBr to get 100% HOBr stream, the following is determined: 484 ppm 40% NaBr x (10.1 lbs 12.5% NaOCl) / (5 lbs 40% NaBr) = 978 ppm 12.5% NaOCl

- Concentration NaCl discharged to outfall = (978 ppm NaOCl/day) x (0.125 active NaOCl) x (0.785 ppm NaCl /100% active NaOCl)/34 (DF) = **2.8 ppm NaCl**

- Concentration NaOH discharged to outfall = 182 ppm HOBr x (40 g/mole NaOH/96.9 g/mole HOBr)/34 (DF) = **2.2 ppm NaOH**

Lower water use limit:

- (248 gal/head x 2000 head/day) x (8.33 lbs/gal process water) = 4,131,680 lbs process water/day (total)

- (40 gallons of FCS treated water/head) x (8.33 lbs/gal) x(2,000 head/day) = 666,400 pounds FCS treated water discharged/day

- 4,131,680 lbs process water / 666,400 pounds FCS treated water = 6:1 dilution factor (DF)

- Assuming no degradation, concentration of HOBr in outfall = (182 ppm HOBr)/6 (DF) = **30 ppm HOBr**

- Concentration of Br^- ion in outfall = 30 ppm HOBr x 0.82 Br-/HOBr = **25 ppm Br^- ion**

- At 182 ppm HOBr: (0.40 NaBr)X x (96.9 g/mole HOBr/103 g/mole NaBr) = 182 ppm HOBr. Solving for X = 484 ppm 40% NaBr

- Using the feed ratio of bleach to 40% NaBr to get 100% HOBr stream, the following is determined: 484 ppm 40% NaBr x (10.1 lbs 12.5% NaOCl) / (5 lbs 40% NaBr) = 978 ppm 12.5% NaOCl

- Concentration NaCl discharged to outfall = (978 ppm NaOCl/day) x (0.125 active NaOCl) x (0.785 ppm NaCl /100% active NaOCl)/6 (DF) = **16 ppm NaCl**

- Concentration NaOH discharged to outfall = 182 ppm HOBr x (40 g/mole NaOH/96.9 g/mole HOBr)/6 (DF) = **12.5 ppm NaOH**

7. Fate of Emitted Substance in the Environment

The expected environmental concentration (EEC) of bromide ion (Br^-) is estimated to be 9.9 ppm from poultry processing. The EEC for bromide in meat processing facilities was estimated to be 4.4 and 25 ppm for the upper and lower water use limits respectively.

The bromide (Br^-) ion would be expected to remain in the wastewater process system and would further be diluted in the receiving body of water. The chemistry would be substantially similar or identical as those for the chloride (Cl^-) ion. Based on the vast amount of information available for chloride, it is expected that bromide ion at the proposed use levels would not create an undue burden on the environment. NaCl is expected to be present at approximately 6.4 ppm in poultry and 2.8 and 16 ppm for the upper and lower water use limits in meat processing respectively. NaOH is expected to be present at approximately 5.0 ppm in poultry and 2.2 and 12.5 ppm for the upper and lower water use limits in meat processing respectively. Both NaCl and NaOH are expected to be dissociated and or neutralized and not expected to present in the outfall at any appreciable amount.

In 2005 the EPA (15) stated that (p. 19): "These results indicate that (sodium) bromide can be used at typical sites without impact most of the time. Since the discharge of hypobromous acid is limited by the NPDES permit program administered by EPA's Office of Water, the Agency will be able to control the discharge of hypobromous acid on a site-by-site basis, so that toxic levels are avoided."

Trihalomethanes are reasonably expected to be formed from reactions of the FCS with organic matter as a result of use. However the FCS is expected to substitute chiefly for cheaper chlorine-based oxidants customarily used in commercial slaughter facilities. Substitution of one halogen-based antimicrobial for another is unlikely to alter in kind existing environmental conditions associated with irreversible ecotoxic effects from exposure, if any, to trihalomethane disinfections by-products discharged into the aquatic or soil environments because such trihalomethanes would be produced whether bromine- or chlorine- based disinfectants are used in the processing operations or in any wastewater treatment of effluents from such operations (16).

8. Environmental Effects of Released Substances

Bromide ion (Br^-) is of low toxicity to aquatic organisms, which would be the target group, assuming most of the bromide in wastewater would be released into other bodies of water. Most of the available data on bromide ion comes from extensive studies from the U.S. EPA. If sodium bromide is released into the environment, it could still be considered identical to the bromide ion (degradate product), due to the fact that sodium bromide dissociates in water to yield free sodium and free bromide ions.

Table 1 below summarizes the aquatic toxicity data of sodium bromide from EPA's Ecotox data set http://cfpub.epa.gov/ecotox/quick_query.htm. Daphnia magna represented the most sensitive species reported. Effect measurement parameters searched were set @ endpoint not reported (NR), statistics no endpoint, end point reported and mortality. Publication years searched were selected beginning year 1980 to present. The data represents the lowest toxicity endpoint (most toxic) reported for that species and study type.

Table 1

D. magna **Aquatic Toxicity Data Summary from ECOTOX for Sodium Bromide (Br^-)**

Test Organism	Endpoint	Duration	Concentration mg/L	Reference
Daphnia magna	LC50	24 hrs	11,000	17
Daphnia magna	LC50	48 hrs	7,451	18
Daphnia magna	LC50	19-day renewal	6,100	17

A sodium bromide dataset was available in the International Uniform Chemical Information Database (IUCLID). Two acute toxicity test results were reported on *Daphnia magna,* see Table 2 below.

Table 2
***D. magna* - Aquatic Toxicity Dataset for Sodium Bromide from IUCLID**

Test Organism	Endpoint	Duration	Concentration mg/L	GLP	Reference
Daphnia magna	LC50/EC50	48 hrs	11,000/5,800	No	17
Daphnia magna	EC50/NOEC	48 hrs	>1,000/=1,000	Yes	19

The highest EEC for Bromide ion was determined to be from the use of the FCS in meat processing facilities using the least amount of water. The EEC in these facilities is estimated to be 25 ppm. Comparing this EEC to the most conservative reported toxicity data, EC50 > 1,000 mg/L, there is a 40-fold safety factor. The most conservative LC50 toxicity value (6,100 mg/L) is 244 times greater than the EEC. Given the bromide ion EEC is much lower than the *Daphnia magna* toxicological endpoints, the bromide ion is not expected to have any significant detrimental effects to the aquatic environment.

The EPA has assessed the ecological effects risk assessment for freshwater and estuarine environments relative to hypobromous acid from activated sodium bromide used in industrial applications (3).

"As discussed earlier, EPA conducted a Tier 1c EEC screening model for hypobromous acid to estimate the maximum concentration that occurs immediately downstream from an industrial point source discharge site. The results for the high exposure case are comparable to the amounts detected in the two Potomac River aquatic residue studies, one of which showed high concentrations of hypobromous acid as far downstream as 80 meters. Based on these studies, the Agency presumes risk to freshwater and estuarine fish and invertebrates at the point of discharge and downstream at 80 meters. However, the modeling results for "typical" sites are well below the levels of concern for fish and invertebrates. These results indicate that activated) sodium bromide can be used at typical sites without impact most of the time. Since discharge of hypobromous acid is limited by the NPDES permit program administered by EPA's Office of Water, the Agency will be able to control the discharge of hypobromous acid on a site-by-site basis so that toxic levels are avoided.

Based on this modeling, EPA also presumes a risk to endangered-freshwater and estuarine/marine organisms in "worst case " situations. However, "typical" discharge levels are below those of concern for endangered species"

The use of inorganic halides in poultry processing is listed as a use pattern subject to U.S. EPA re-registration with use levels ranging from 150-300 parts per million in the facility (page 25 of the RED document (4). Additionally, the U.S. EPA published a Tolerance Reassessment Decision Document (TRDD). The Ecological Risk Characterization was based on the documents published in the RED for Inorganic Halides (5). The EPA concluded:

"The current uses of sodium and potassium bromide have been evaluated and it is concluded that there is a reasonable certainty that the use of products ... will not pose harm to the general

population or any population subgroup. It is further acknowledged that additional uses for these products do exist and that the RED *for bromide should be consulted for additional information on quantitative risks associated from the use of other bromide-containing products."*

Considering that bromide ion, derived from the degradation of hypobromous acid in the presence of organic matter, has a relative benign environmental profile as established by the U.S. EPA, and that discharges will be controlled with an NPDES permit, we submit there will be no adverse environmental impact associated with its use and discharge.

9. Use of Resources and Energy

The product is part of a treatment program to reduce the numbers of and inhibit the growth of pathogens and other microorganisms in wash water for purposes of food safety. Any initial expenditure of energy used to create the FCS will be realized through savings in reduced usage of wash water and reduction in product recalls due to contamination.

10. Mitigation measures

The proposed FCS is not reasonably expected to result in any new or extraordinary environmental problems that would require mitigation measures of any kind. The FCS is a relatively benign compound that may replace other more toxic compounds in use presently. In addition, discharge permits are mandated by the National Pollutant Discharge Elimination System (NPDES), in which all pollutants or components of discharges are reported by the discharger, and monitored and controlled by each state and region within a state.

11. Alternatives to the proposed action

GE Water & Process Technologies believes no potential adverse environmental effects are identified that would necessitate alternative actions to the proposed use of the HOBr.

12. List of Prepares:

C. J. Sinko, MSc., - Product Stewardship Specialist V, GE Water and Process Technologies

13. Certification

The undersigned officials certify that the information presented is true, accurate and complete to the best of the knowledge of our firm responsible for preparation of the Environmental Assessment.

Date: 7/20/11

Signature of Responsible Official: [redacted]

Title: Product Stewardship Specialist V

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